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UNITED STATES DEPARTMENT OF COMMERCE
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November 16, 2004

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Certified by



Jon W Dudas

Acting Under Secretary of Commerce for Intellectual Property and Acting Director of the U.S. Patent and Trademark Office

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PROVISIONAL APPLICATION FOR PATENT COVER SHEET This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

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| Bharat A. | M | lehta | | Bloomfield Hills | , Michiga | n | 3917 U 60/509 | |
| Additional inventors are be | Additional inventors are being named on the separately numbered sheets attached hereto | | | | | | | |
| TITLE OF THE INVENTION (280 characters max) PLATFORM CATHETER | | | | | | | | |
| Direct all correspondence to: | | CORRESPO | ONDENCE | ADDRESS | | | | |
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| METHOD OF PAYMENT OF FIL | METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT (check one) | | | | | | | |
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| Applicant claims small entity status. See 37 CFR 1.27. A check or money order is enclosed to cover the filing fees The Commissioner is hereby authorized to charge filing fees or credit any overpayment to Deposit Account Number 11-1449 Payment by credit card. Form PTO-2038 is attached. | | | | | | | | |
| The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government. No. Yes, the name of the U.S. Government agency and the Government contract number are: | | | | | | | | |
| Respectfully submitted, SIGNATURE | | 2) | | | 10/7/0. | - | 1 | 7 |
| TYPED or PRINTED NAME Amy E. Rinaldo (if appropriate) | | | | | | \exists | | |
| Docket Number: 1059.00076 | | | | | 0/0 | | | |

USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

This collection of information is required by 37 CFR 1.51. The information is used by the public to file (and by the PTO to process) a provisional application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 8 hours to complete, including gathering, preparing, and submitting the complete provisional application to the PTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Box Provisional Application, Assistant Commissioner for Patents, Washington, D.C.

PROVISIONAL APPLICATION COVER SHEET Additional Page

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| INVENTOR(S)/APPLICANT(S) | | | | | | | | | |
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Attorney Docket No: 1059.00076

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PROVISIONAL PATENT APPLICATION

PLATFORM CATHETER

10 BACKGROUND OF THE INVENTION

TECHNICAL FIELD

The present invention relates to a catheter. More specifically, the present invention relates to a platform catheter.

BACKGROUND ART

Cerebral aneurysms are enlargements of the cerebral vasculature,
which protrude like a balloon from the wall of a cerebral artery. The cerebral
aneurysm has a neck that leads to the parental vessel and a body or "dome"
that can vary in diameter from 1-30 mm.

The wall of the aneurysm is often weak and can rupture, leading to hemorrhage. Rupture of the aneurysm can kill a patient or leave the patient with permanent or transitory mental and physical deficits.

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Aneurysms are often treated to prevent rupture that can lead to hemorrhage, or to prevent rebleeding of acutely ruptured aneurysms. A conventional method of treating aneurysms is to fill the aneurysm with coils. The coils are introduced into the aneurysm one at a time through a delivery catheter until the aneurysm is filled. The aneurysm eventually becomes a solid mass of coils and thrombi.

A problem with the conventional method of using coils to fill aneurysms is that the aneurysm becomes a relatively solid mass due to coils and thrombi contained therein. The mass of coils and thrombi exert pressure on adjacent areas of the brain, which may lead to other problems. Another problem with the conventional method is that the coils must be delivered one at a time into the aneurysm, which increases the procedure time and risk to the patient. For large aneurysms, up to twenty coils may be required to fill the aneurysm.

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It is an object of the invention to provide improved methods and devices for treating aneurysms. These and other objects of the invention will

become evident from the description of the preferred embodiments described below.

DESCRIPTION OF THE INVENTION

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Generally, the present invention provides a platform catheter and method of using the same. The catheter is a modification of an existing microcatheter tip. The parts of the catheter are made of materials known to those of skill in the art that are sufficient to perform the method of the present invention.

A ring of hydrogel is attached to the tip of a microcatheter. The ring is able to expand up to three times its original dimensions. The ring creates a sufficient platform at the base of a wide neck aneurysm. The head is made of a material known to those of skill in the art that is sufficient to create a platform. The catheter is shown in more detail in the attached drawings.

The present invention comprises a platform catheter, utilizable for the removal of an aneurysm from a body artery or vein. Such a catheter is made from a polymeric material or other materials known to those of skill in the art.

The present invention provides a treatment of abnormalities in a

patient's vascular system. A specific use of the present invention described below is for the treatment of cerebral aneurysms, although the various aspects of the invention described below also may be useful in treating other abnormalities such as arteriovenous malformations (AVM), hypervascular tumors, cavernous carotid fistulas, fibroid tumors, and non-reversible sterilization via fallopial occlusion.

A detailed description of the platform catheter is set forth in Appendix A included herewith and incorporated by reference in its entirety.

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Throughout this application, various publications, including United States patents, are referenced by author and year, and patents, by number. Full citations for the publications are listed below. The disclosures of these publications and patents in their entireties are hereby incorporated by reference into this application in order to more fully describe the state of the art to which this invention pertains.

The invention has been described in an illustrative manner, and it is to be understood that the terminology that has been used is intended to be in the nature of words of description rather than of limitation.

Obviously, many modifications and variations of the present invention

are possible in light of the above teachings. It is, therefore, to be understood that within the scope of the described invention, the invention may be practiced otherwise than as specifically described.

APPENDIX A

Platform Catheter

Currently "wide neck" (more than 4 to 5mm) cerebral aneurysm treatment by endovascular technique requires additional help by balloon remodeling technique i.e. a 2^{nd} microcatheter with an inflatable balloon is required in the parent artery. The balloon catheter is parked across the wide neck of aneurysm, while the primary microcatheter tip is parked within the sac of aneurysm. Platinum coils are deposited within the sac of wide neck aneurysm while the balloon is inflated in the parent artery, across the neck of wide neck aneurysm, thus preventing coil migration into the parent artery.

Balloon needs to be deflated periodically to prevent acute ischemia in the distal territory of parent artery. Currently this is a well accepted method of endovascular treatment of wide neck aneurysm. However, this is by no means easy or safe all the time and requires significant expertise and experience on the part of the operator.

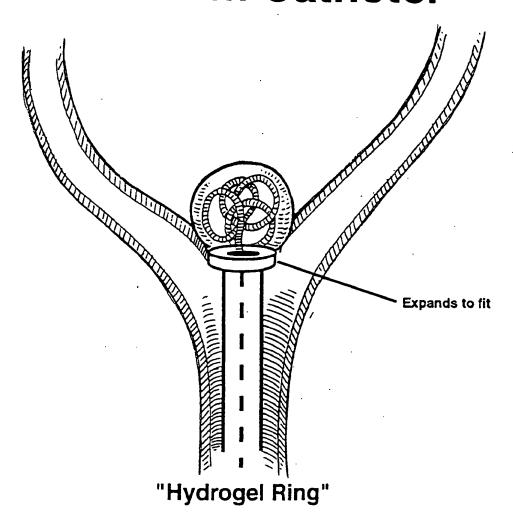
This platform catheter concept is very simple and elegant because it eliminates use of 2nd balloon catheter. A ring of Hydrophilic material (i.e. Hydrogel) is attached to tip of primary microcatheter, which is going to deliver Platinum coils into the sac of wide neck aneurysm, swells to a larger diameter (from initial dehydrated state). This enlarged platform provides sufficient support to coil mass in the sac of wide neck aneurysm and blocks/prevents migration of coil loops into the parent artery, there by obviating need for additional balloon catheter.

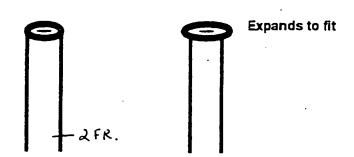
Currently more than 50,000 cerebral aneurysms are treated annually world wide, and this rate is growing 20% annually. More than 60-70%. Aneurysms are treated by balloon assisted method. This platform catheter can safely replace the need for 2nd balloon catheter in most instances.

Platform catheter can replace currently available single tip microcatheter in most instances and can be used as the primary microcatheter.

The construction of this platform catheter is a simple modification of existing microcatheter tip. A ring of Hydrogel is attached to the tip of microcatheter. This ring can expand and up to 2 or 3 times its original dimension; there by providing sufficient platform at the base of wide neck aneurysm, so aneurysm greater than 4mm. Wide neck to 8 to 10mm. Wide neck can be treated without the need for balloon occlusion cataheter in the parent artery.

Platform Catheter





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